

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 68603.507DV2)

In re Application of: Sullivan et al.) Examiner: To Be Assigned
Serial No: 10/607,695)
Filed: June 27, 2003)
Title: IN VIVO INDUCTION FOR ENHANCED FUNCTION OF ISOLATED HEPATOCYTES

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below.

Date: 4/9/04

Sarah Farris
Sarah Farris

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.56, Applicants submit herewith the attached Form PTO-1449 for filing in the above-referenced application. The present application is a divisional of U.S. Patent Application No. 10/036,593 (now U.S. Patent No. 6,699,716), which is a divisional of U.S. Patent Application No. 09/621,921 (now U.S. Patent No. 6,394,812), which claims benefit of U.S. Provisional Application No. 60/145,362. The attached Form PTO-1449 lists references that were already submitted by the Applicants or cited by the Examiners in the non-provisional parent applications; therefore, pursuant to 37 C.F.R. § 1.98 (d), no copies of the previously cited art are enclosed. This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97 (b) (3), before the mailing date of a first Office Action on the merits; therefore, no fee is believed to be due.

This submission does not represent that a search has been made and does not constitute an admission that the listed documents are material to the patentability of the invention, or that the listed documents are prior art. Applicants reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application. If it should be determined that any of the listed documents constitute prior art under United States law, Applicants reserve the right to present to the Office relevant facts and law regarding the significance of such documents to the patentability of the claimed invention.

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Supplemental Information Disclosure Statement
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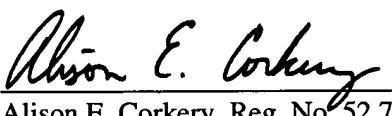
It is respectfully requested that the Examiner initial and return copies of the enclosed Form PTO-1449 with the next Patent Office communication.

Please charge any fees that might be due in connection with this matter to Deposit Account No. 08-0219. If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

Date: April 9, 2004

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**INFORMATION DISCLOSURE
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number
68603-507DV2Application Number
10/607,695Applicant
Sullivan, et al.

Sheet	1	OF	2	Filing Date	Group Art Unit
				June 27, 2003	1651

U.S. Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,030,105	7/9/1991	Kuri-Harcuch, et al.			
	5,445,956	8/29/1995	Hammock, et al.			
	5,466,696	11/14/1995	Woolf			
	5,506,131	4/9/1996	Harris, et al.			
	5,576,207	11/19/1996	Reid, et al.			
	5,602,026	2/11/1997	Dunn et al.			
	5,658,797	8/19/1997	Bader			
	5,866,420	2/2/1999	Talbot, et al.			
	5,869,243	2/9/1999	Jauregui, et al.			
	5,942,436	8/24/1999	Dunn et al.			
	6,127,117	10/3/2000	Morris, et al.			
	6,394,812	05/2002	Sullivan et al.			

Foreign Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	96/34087	10/31/96	WO				

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

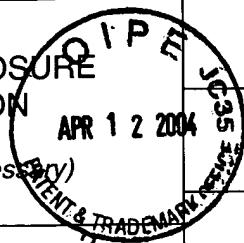
A1	Asaka et al., "Localization of xenobiotic responsive element binding protein in rat hepatocyte nuclei after methylcholanthrene administration as revealed by in situ southwestern hybridization," J. of Histochem. & Cytochem., Vol. 46, No. 7, pp. 825-832 (1998)
A2	Baron et al. Effects of 3-methylcholanthrene, β -naphthoflavone and phenobarbital on the 3-methylcholanthrene-inducible isozyme of cytochrome p-450 within centrilobular, midzonal and periportal hepatocytes (1982) J. Biol. Chem., Vol. 257, No. 2, pages 953-7.
A3	Bhatia, S.N. et al., "Microfabrication of Hepatocyte/Fibroblast co-cultures: Role of Homotypic cell interactions," Biotechnol. Prog., Vol. 14, pp. 378-387 (1998)
A4	Bhatia, S.N. et al., "Effect of cell-cell interactions in preservation of cellular phenotype: cocultivation of hepatocytes and nonparenchymal cells," FASEB, Vol. 13, pp. 1883-1900 (1999)
A5	Cottrell et al., "Strain specific enhancement or inhibition of coumarin hepatotoxicity in mince following pretreatment with two different liver enzyme inducing agents," Fundamental and Applied Toxicology, Vol. 34, pp. 47-55 (1996)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.

**INFORMATION DISCLOSURE
IN AN APPLICATION**

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Sheet	2	OF	2	Filing Date	Group Art Unit
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Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

A6	Jauregui, H.O. et al, "Xenobiotic induction of P-450 PB-4 (IIB1) and P-450-c (IA1) and associated monooxygenase activities in primary cultures of adult rat hepatocytes," <i>Xenobiotica</i> , Vol. 21, No. 9, pp. 1091-1106 (1991)
A7	Jones, E.A. et al., "Hepatic encephalopathy and benzodiazepine receptor ligands," in <i>Hepatic Encephalopathy: Pathophysiology and Treatment</i> (Butterworth and Layrargues eds.) Humana Press (Clifton, NJ) pp. 273-286 (1989)
A8	Monshouwer et al., Characterization of cytochrome p450 isoenzymes in primary cultures of pig hepatocytes (Dec. 1998) <i>Toxicology in Vitro</i> , Vol. 12, pages 715-723.
A9	Morel et al. Preferential increase of glutathione s-transferase class α transcripts in cultured human hepatocytes by phenobarbital, 3-methylcholanthrene, and dithiolethiones (1993) <i>Cancer Research</i> , Vol. 53, pages 231-234.
A10	Naik, S. et al, "Isolation and culture of porcine hepatocytes for artificial liver support," <i>Cell Transplantation</i> , Vol. 5, No. 1, pp. 107-115 (1996)
A11	Nishibe, Y. et al., "Induction of cytochrome P-450 isoenzymes in cultured monkey hepatocytes," <i>Int. J. Biochem. Cell Biol.</i> , Vol. 27, No. 3, pp. 279-285 (1995)
A12	Nishibe et al., Effects of phenobarbital and other model inducers on cytochrome p450 isozymes in primary culture of dog hepatocytes (1993) <i>Xenobiotica</i> , Vol. 23, No. 6, pages 681-692.
A13	Nyberg, S. et al., "Pharmacokinetic analysis verifies P450 function during in vitro and in vivo application of a bioartificial liver," <i>ASAIO Journal</i> , pp. M252-M256 (1993)
A14	Oinonen et al., "Pretranslational induction of cytochrome P4501 A enzymes by β-naphthoflavone and 3-methylcholanthrene occurs in different liver zones," <i>Biochemical Pharmacology</i> , Vol. 48, No. 12, pp. 2189-2197
A15	Seglen, P.O., "Preparation of isolated rat liver cells," in <i>Methods in Cell Biology</i> , (DM Prescott ed.) vol. 13, Academic Press (NY, NY) pp. 29-83 (1976)
A16	Silva et al., "Induction of cytochrome-p450 in cryopreserved rat and human hepatocytes," <i>Chemico-Biological Interactions</i> , Vol. 121, pp. 49-63 (1999)
A17	Thomas, P.E. et al., "Induction of two immunochemically related rat liver cytochrome P-450 isozymes, cytochromes P-450c and P-450d, by structurally diverse xenobiotics," <i>Journal of Biological Chemistry</i> , Vol. 258, No. 7, pp. 4590-4598 (1983)
A18	van't Klooster et al., Cytochrome p450 induction and metabolism of alkoxyresorufins, ethylmorphine and testosterone in cultured hepatocytes from goats, sheep and cattle (1993) <i>Biochemical Pharmacology</i> , Vol. 46, No. 10, pp. 1781-1790.

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TRANSMITTAL LETTER

Dear Sir:

Enclosed for filing in the above-identified patent application are the following documents:

1. Supplemental Information Disclosure Statement (2 pages);
2. Form PTO-1449 (2 pages);
3. Certificate of First Class Mailing; and
4. Return Postcard.

No fees are believed to be due in connection with this submission. However, please charge any fees that might be due or credit any overpayment to our Deposit Account No. 08-0219. If there are any questions, please call the undersigned at the number below.

Respectfully submitted,

Date: April 9, 2004
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Alison E. Corkery
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